

FY02
Total BPD Reports

	NUMBER OF REPORTING ESTABLISHMENTS	TOTAL REPORTS RECEIVED	POTENTIAL RECALLS	
BLOOD/PLASMA MANUFACTURERS				
LICENSED BLOOD ESTABLISHMENTS	224/*169	21852	1481	6.8%
UNLICENSED BLOOD ESTABLISHMENTS ¹	383	5142	157	3.1%
TRANSFUSION SERVICES ²	472	1304	2	0.2%
PLASMA CENTERS	361/*62	5168	533	10.3%
<i>SUB-TOTAL</i>	1440	33466	2173	6.5%
NON-BLOOD MANUFACTURERS				
ALLERGENICS MANUFACTURER	8	273	14	5.1%
BLOOD DERIVATIVE MANUFACTURER	17	45	5	11.1%
IN-VITRO DIAGNOSTIC MANUFACTURER	11	93	13	14.0%
THERAPEUTIC MANUFACTURER	13	23	4	17.4%
VACCINE MANUFACTURER	10	42	4	9.5%
<i>SUB-TOTAL</i>	59	476	40	8.4%
TOTAL	1499	33942	2213	6.5%

¹Unlicensed Blood Establishments – unlicensed blood establishments performing manufacturing of blood and blood components that require registration with FDA

²Transfusion Service – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not be registered with FDA.

*Number of license holders; may be one or more establishments operating under one license.

FY01 vs FY02
Total BPD Reports

	#Reporting Establishments		Total Reports		Potential Recall	
	FY01	FY02	FY01	FY02	FY01	FY02
BLOOD/PLASMA MANUFACTURERS						
LICENSED BLOOD ESTABLISHMENTS	376/*123	224/*169	19398	21852	1406	1481
UNLICENSED BLOOD ESTABLISHMENTS	247	383	1039	5142	22	157
TRANSFUSION SERVICES	277	472	519	1304	0	2
PLASMA CENTERS	345/*44	361/*62	4013	5168	242	533
<i>SUB-TOTAL</i>	1245	1440	24969	33466	1670	2173
NON-BLOOD MANUFACTURERS						
ALLERGENIC	9	8	243	273	13	14
DERIVATIVE	15	17	56	45	4	5
IN-VITRO DIAGNOSTIC	9	11	28	93	18	13
THERAPEUTIC	11	13	19	23	7	4
VACCINE	11	10	52	42	1	4
<i>SUB-TOTAL</i>	55	59	398	476	43	40
TOTAL	1300	1499	25367	33942	1713	2213

*Number of license holders; may be one or more establishments operating under one license.

FY01 vs FY02
Blood & Plasma BPDs
By Manufacturing System

MANUFACTURING SYSTEM	FY01		FY02	
<i>DONOR SUITABILITY</i>	19556	82.1%	25312	75.6%
POST DONATION INFORMATION	18256	76.6%	23162	69.2%
DONOR SCREENING	1210	5.1%	2032	6.1%
DONOR DEFERRAL	90	0.4%	118	0.4%
<i>QC & DISTRIBUTION</i>	1892	7.9%	3875	11.6%
<i>LABELING</i>	1313	5.5%	2367	7.1%
<i>PRODUCT TESTING</i>	624	2.6%	1120	3.3%
ROUTINE TESTING	542	2.3%	1039	3.1%
VIRAL TESTING	82	0.3%	81	0.2%
<i>COMPONENT PREPARATION</i>	264	1.1%	424	1.3%
<i>COLLECTION</i>	150	0.6%	207	0.6%
<i>MISCELLANEOUS</i>	40	0.2%	161	0.5%
TOTAL	23839	100%	33466	100.0%

FY01 vs FY02
Non-Blood BPDs
By Manufacturing System

Manufacturing System	Allergenic		Derivative		In-Vitro Diagnostic		Therapeutic		Vaccine		Total	
	FY01	FY02	FY01	FY02	FY01	FY02	FY01	FY02	FY01	FY02	FY01	FY02
Incoming Material	2	1	8	3	0	2	1	2	1	0	12	8
Process Controls	6	0	6	7	4	30	2	7	5	10	23	54
Testing	1	2	1	4	1	11	0	4	5	10	8	31
Labeling	27	29	7	4	10	11	1	1	6	3	51	48
Product Specifications	183	225	23	20	6	29	10	6	32	17	254	297
Quality Control & Distribution	5	15	11	7	5	7	3	3	1	2	25	34
Miscellaneous	0	1	0	0	1	3	0	0	1	0	2	4
<i>Total</i>	<i>243</i>	<i>273</i>	<i>56</i>	<i>45</i>	<i>28</i>	<i>93</i>	<i>19</i>	<i>23</i>	<i>52</i>	<i>42</i>	<i>398</i>	<i>476</i>

The on-line electronic BPD report form was implemented on June 18, 2001. 32.9% of the reports received in FY02 were submitted electronically.

Reports Submitted Electronically

	Total Reports	# of eBPDR	% eBPDR
BLOOD/PLASMA MANUFACTURERS			
LICENSED BLOOD ESTABLISHMENTS	21852	7213	33.0%
UNLICENSED BLOOD ESTABLISHMENTS	5142	2014	39.2%
TRANSFUSION SERVICES	1304	840	64.4%
PLASMA CENTERS	5168	920	17.8%
<i>SUB-TOTAL</i>	<i>33466</i>	<i>10987</i>	<i>32.8%</i>
NON-BLOOD MANUFACTURERS			
ALLERGENIC	273	135	49.5%
DERIVATIVE	45	3	6.7%
IN-VITRO DIAGNOSTIC	93	29	31.2%
THERAPEUTIC	23	5	21.7%
VACCINE	42	3	7.1%
<i>SUB-TOTAL</i>	<i>476</i>	<i>175</i>	<i>36.8%</i>
TOTAL	33942	11162	32.9%